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Docket No. G-091US02REG
Serial No. 09/924,340Remarks

Claims 34-49 are pending in the subject application. By this Amendment, Applicants have canceled claims 41-46 and amended claim 37. Support for the amendments can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 34-40 and 47-49 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

The Examiner has indicated that the title of the invention is not descriptive and that a new title is required that is clearly indicative of the invention to which the claims are directed. Applicants have amended the title of the invention to "vCOL16A1 Polypeptides." Accordingly, reconsideration and withdrawal of this objection is respectfully requested.

The disclosure is objected to because it contains embedded hyperlinks or other forms of browser executable code. Applicants respectfully submit that this issue is moot in view of the amendment made to the specification. The subject application has also been amended in order to properly cite trademarks and correct other minor typographical errors. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claims 37, 40, 43, 46, and 49 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants respectfully assert that the claims as filed are definite. The Office Action indicates that claim 37 is vague and indefinite because it is not clear how "six consecutive amino acids" would fit into "positions 97 through 98." Applicants respectfully submit that claim is not vague or indefinite. Applicants respectfully submit that the plain reading of the claim indicates that the claimed fragment is at least six consecutive amino acids of SEQ ID NO: 58 and that the fragment also spans positions 97-98 of SEQ ID NO: 58. However, in the interest of expediting prosecution in this matter, Applicants have amended claim 37 to more clearly indicate this aspect of the invention. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 34-49 are rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, on the ground that the claimed invention is not supported by a well-established utility. The Office Action argues that the utilities indicated within the specification are non-specific or particular to the claimed

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sequence. For example, the Office Action argues that the use of the claimed sequence as a substrate for various proteases, in animal models, for the diagnosis of diseases or disorders associated with abnormalities of the metabolism of collagen or the monitoring of collagen degradation are non-specific uses that are applicable to a large family of structurally related collagen related proteins and which are not specific to the polypeptide being claimed. Applicants respectfully traverse.

As set forth in the specification, the instantly claimed invention has utility for: the diagnosis of diseases or disorders associated with abnormalities of the metabolism of collagen; use in assays (*in vitro*) as a substrate of proteases; the treatment of diseases and conditions associated with collagen matrix destruction, including for wound treatment; for preparing cosmetic compositions such as skin creams with anti-wrinkle activity; or use as an injectable biomaterial.

Applicants respectfully submit that the fact that the claimed polypeptide has certain uses that overlap with other structurally related proteins is not controlling as to whether the claimed polypeptide has a utility that is specific, credible, substantial or well-established. For example, the subject specification indicates that the claimed polypeptide can be used as an injectable biomaterial or in cosmetic compositions. As the Patent Office may be aware, injectable collagen is used in the fields of plastic surgery for a variety of purposes, including for lip augmentation and to rectify facial defects, frown lines and acne scars (see paragraph 983 of the published application). As discussed in the specification, as-filed, the claimed variant of the human alpha 1 type XVI collagen contains two collagen triple helix repeat domains (positions 11-70 and 73-131; see paragraph 972 of the published application). Thus, it is respectfully submitted that one skilled in the art would recognize that the instantly claimed invention would have a specific, credible, substantial and well-established utility for use in the field of plastic surgery. Further, it is respectfully submitted one skilled in the pertinent arts would be able to use the subject invention in view of the teachings of the application and/or the skill of the artisan of the relevant field of endeavor. Accordingly, reconsideration and withdrawal of the rejections is respectfully requested.

Claims 41-46 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully assert that there is adequate written description in the subject

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specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention; however, in the interest of expediting prosecution in this matter, Applicants have cancelled these claims without prejudice. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 37, 40-43, 46, and 49 are rejected under 35 U.S.C. § 102(b) as anticipated by Pan *et al.* (1992). The Office Action states that the Pan *et al.* reference discloses a cDNA sequence encoding the human alpha 1 type V XI collagen polypeptide which is inherently an allelic variant of the claimed polypeptide. Applicants respectfully submit that the cited reference fails to anticipate the presently claimed invention. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

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Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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